REMARKS

This Replacement Amendment is submitted in response to the 28 July 2005 Notice of Non-Compliant Amendment. These remarks being timely filed, no fee is believed required.

The PTO Form 892

Applicant thanks the Office for reviewing the Petition and the accompanying prior art references included in it. Because the Office has considered these references, Application respectfully requests that they be listed on a PTO Form 892. This will better apprise the public of the scope of the art of record in this case.

Priority

Applicant acknowledges the Examiner's need for a certified copy of the priority application. Applicant will provide it as soon as it is available.

Response To Amendment

The OFFICE ACTION (17 Dec 2004) notes (at page 2), "The Preliminary Amendment filed 01/30/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure."

Reconsideration is requested, because the PRELIMINARY AMENDMENT is part of the original disclosure. *See* MANUAL OF PATENT EXAM. PROC. § 608.04(b) (Aug. 2001) (an amendment "filed along with the filing of the application" is "considered a part of the original disclosure"); 608.01(l) ("applicant may rely not only on the description and drawings as filed, but alos on the original claims").

In the immediate case, the application was filed on 01/30/04. *See* FILING RECEIPT (2004). The PRELIMINARY AMENDMENT accompanied the application. *See* OFFICE ACTION (17 Dec

2004) at page 2 ("The Preliminary Amendment [was] filed 01/30/04"). Because it accompanied the application, the PRELIMINARY AMENDMENT is respectfully believed part of the original disclosure. It therefore should not be objected to as adding new matter to the original disclosure.

The MANUAL OF PATENT EXAM. PROC. notes that in this situation, "the claim should be treated on the merits, and requirement made to amend the drawing and description to show this subject matter." *Id.* at § 608.01(l) (Aug. 2001). Applicant thanks the Examiner for "treating the claims on the merits"; Applicant accordingly amends the description to reiterate the disclosure of the claims.

Claim Rejections – 35 U.S.C. Section 112, First Paragraph

Claims 26 - 30, 32, 34 and 36 stand rejected as failing to comply with Section 112, first paragraph, because the Specification fails to recite *in haec verba* various terms used in these claims.

Reconsideration is requested because the Examiner's concern appears to be more properly raised not under Section 112, but under MANUAL OF PATENT EXAM. PROC. § 608.01(l). Applicant accordingly amends the Specification by copying these claim terms from the Claims into the Specification. This amendment is believed to satisfy the Examiner's concern.

Claim Rejections – 35 U.S.C. Section 112, First Paragraph

Claim 33 stands rejected as failing to comply with Section 112, second paragraph. The claim uses the term "pharmaceutically acceptable material." The Examiner correctly notes that the specification does not define "pharmaceutically acceptable material." The Examiner asks, "What is pharmaceutically acceptable material?"

Reconsideration is requested, because Applicant intends the term have its ordinary meaning. I attach pages from MERRIAM WEBSTER'S COLLEGIATE DICTIONARY (10th ed., 1996), showing the definitions of the words "pharmaceutical," "acceptable" and "material." I believe each is clearly defined.

I note also that the phrase "pharmaceutically acceptable" appears in a large number of issued patent claims; so many, in fact (over 6,500) that when I tried to search this claim term in the Patent Office's on-line database, my search was automatically stopped by the Patent Office's database search engine as covering too many patents. I nonetheless attach as examples the first pages of a random sample of fifty (50) recently-allowed patents, each of which recites this claim language.

I note that as part of establishing a *prima facie* case, the Office bears the burden of proposing alternative language which would be more clear than the disputed term:

> In cases where a sound rejection on the basis of prior art which discloses the "heart" of the invention (as distinguished from prior art which merely meets the terms of the claims), secondary rejections on minor technical grounds should ordinarily not be made. Certain technical rejections (e.g. negative limitations, indefiniteness) *should not be made* where the examiner, recognizing the limitations of the English language, *is not aware of an improved mode of definition.*

MANUAL PATENT EXAM. PROC. § 707.07(g) (2001). Here, Applicant is open to considering any proposals the Examiner may have for an "improved mode of definition." If the Office does not suggest an "improved mode," however, the indefiniteness rejection should not be made. Id. Reconsideration is therefore respectfully requested.

Claim Rejections – Anticipation

Claims 33 and 35 stand rejected as anticipated by CHEN *et al.* U.S. '805. Claims 26, 28 and 29 stand rejected as anticipated by BUXTEN et al., U.S. '845.

Reconsideration is respectfully requested in light of the appended amendments.

Pharmaceuticals come in a variety of formulations. These include normal release and controlled release. Normal release formulations release the drug into the patient's gastro-intestinal tract as fast as the tablet can physically dissolve. In contrast, "controlled release" formulations release the drug over a controlled (e.g., extended) period of time. Controlled release is desirable where the drug is best utilized, for example at a slow, measured rate (for example, a once-a-day or once-a-week tablet). In contrast, normal release is used where a relatively-sudden release of a relatively-large amount of the drug is acceptable.

Reading the references as a whole (which we must do), CHEN and BUXTON teach controlled release formulations. *See* CHEN at col. 2, line 65; col. 3, line 13 *et seq.*; claims 1 to 18; see BUXTON at col. 3, lines 3 et seq.

In contrast, the claimed invention is drawn to a normal release formulation. The claimed invention does not provide controlled release. Rather, it provides normal release, but, before the drug is used, provides a shelf-stabile form which improves the stability of the drug product, by preventing it from absorbing atmospheric water before use. Because the claimed invention is drawn to a normal release product, the most-pertinent references are not CHEN and BUXTON, but ELDER (WO 99/58116), CHICKERING (US 2004/0121003), COHEN (US 2003/015230), FELUMB (US 2004/0072912), PATHAK '944 (US 6,113,944) and PATHAK '842 (US 6,007,842), each drawn to a methods to improve the shelf-life stability of paroxetine drug products..

The claims have been amended to clarify this difference.

Claim Rejections - Obviousness

Claims 26 to 36 stand rejected as obvious in light of BUXTON combined with CHEN. Reconsideration is respectfully requested in light of the immediate amendments.

Obviousness requires determining the scope and contents of the prior art. In the immediate case, the prior art relied on teaches controlled release formulations. The art relied upon does not, however, teach any normal release formulation.

The Examiner recognizes that the art of record fails to teach the claimed surfactant : ethyl cellulose ratio. The Examiner also recognizes that such differences in concentration will not support patentability unless there is evidence that such ratio is critical. In the immediate case, this difference is in fact critical, because changing the ratio of surfactant to ethyl cellulose will change the dissolution profile of the product, and may in so doing change a "normal release" formulation into a "controlled release" formulation. Thus, this ratio is in fact. critical

Summary

Reconsideration and allowance of the amended claims is respectfully believed warranted.

Respectfully submitted,
PHARMACEUTICAL PATENT ATTORNEYS, LLC

/s/

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